

Beckman Instruments, Inc., Section 510(k) Notification
SYNCHRON® Systems 10 ng/mL and 40 ng/mL THC Urine Controls
Summary of Safety & Effectiveness

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K971210

1.0 **Submitted By:**

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2.0 **Date Submitted:**

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3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems 10 ng/mL THC Urine Control
SYNCHRON® Systems 40 ng/mL THC Urine Control

3.2 **Classification Names**

Clinical Toxicology Control Material (21 CFR § 862.3280)

4.0 **Predicate Device(s):**

Δ⁹ Cannabinoid Urine Controls, Diagnostic Reagents, Inc. (DRI), K932113

5.0 **Description:**

The SYNCHRON® Systems 10 ng/mL and 40ng/mL THC Urine Controls, are ready-to-use, human urine based liquid controls designed to be used as part of a laboratory total quality management program to ensure proper THC assay performance. These controls complement the current panel of

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SYNCHRON® Systems Cannabinoid reagents and controls previously cleared by the FDA. The kit consists of 1 x 5.0 mL bottle and must be stored at +2°C to + 8°C.

6.0 Intended Use:

The SYNCHRON Systems 10 ng/mL and 40 ng/mL THC Urine Controls, in conjunction with the SYNCHRON Cannabinoid 20 ng (THC2) Reagent, are intended for use on SYNCHRON Systems for monitoring the quality control of cannabinoid (THC) testing in the clinical laboratory. These controls are designed for use with the family of SYNCHRON Systems which include analyzers such as the SYNCHRON CX4, CX4CE, CX4 DELTA, CX5, CX5CE, CX5 DELTA, CX7, CX7 DELTA Systems and LX™20 Systems.

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7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
SYNCHRON Systems 10 and 40 ng/mL THC Urine Controls	Liquid, ready-to-use, human urine matrix control.	Same as DRI
	Intended use (for monitoring the quality control of THC enzyme immunoassays)	Same as DRI
	Manufacturing process and qualification	Same as DRI
DIFFERENCES		
SYNCHRON Systems 10 and 40 ng/mL THC Urine Controls	Labeling	Controls are labeled at DRI using Beckman labels and insert
	Limitations for use	Controls are to be used only with SYNCHRON Systems and SYNCHRON Cannabinoid 20 ng (THC2) Reagent
	Concentration of THC in the 10 ng/mL control	The concentration level of THC in the lower control is 10 ng/mL

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8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to a control test system already in commercial distribution. Equivalence is demonstrated through stability and imprecision studies that relate results obtained from the SYNCHRON® Systems 10 ng/mL and 40 ng/mL THC Urine Controls to the DRI Δ⁹ Cannabinoid Urine Controls.

Stability Study Results

Reagent	Product Claim
SYNCHRON® Systems 10 ng/mL and 40ng/mL THC Urine Controls	24 month shelf-life

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Precision Study Results
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Material	Mean (mA/min)	SD (mA/min)	%CV	Number of Results
Negative Calibrator	262.40	0.95	0.36	20
THC Control 1 (10 ng/mL)	272.36	1.45	0.53	20
Low Calibrator (20 ng/mL)	283.32	1.30	0.46	20
THC Control 2 (40 ng/mL)	306.98	1.52	0.49	20
High Calibrator (50 ng/mL)	319.38	1.32	0.41	20

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.